

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P168302PC-MA	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/006266	International filing date (day/month/year) 13 June 2003 (13.06.2003)	Priority date (day/month/year) 13 June 2002 (13.06.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/48, A61P 25/14		
Applicant NEUROBIOTEC GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 14 August 2003 (14.08.2003)	Date of completion of this report 21 July 2004 (21.07.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/006266

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1-12 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____ 1-11 _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Intern application No.
PCT/EP 03/06266

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-5, 10	YES
	Claims	6-9, 11	NO
Inventive step (IS)	Claims	1-5	YES
	Claims	6-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: DE4240798

D2: US4711891

D3: OLBRICH R ET AL: "AN EVALUATION OF THE PARTIAL DOPAMINE AGONIST TERGURIDE REGARDING POSITIVE SYMPTOMS REDUCTION IN SCHIZOPHRENICS" JOURNAL OF NEURAL TRANSMISSION, SPRINGER VERLAG, VIENNA, AT, Vol. 84, No. 3, 1991, pages 233-236.

The present application fails to meet the requirements of PCT Article 33(1) since the subject matter of claims 6 to 9 and 11 is not novel within the meaning of PCT Article 33(2).

D1 discloses pharmaceutical compositions containing ergot derivatives for neuroprotection purposes. In particular, the example on page 4, lines 19 to 23, describes a composition containing lisuride as active substance.

D2 describes methods of treating the reduction in cognitive and motor functions, characterized in that the methods include the administering of terguride.

D3 describes the administering of terguride to schizophrenic patients.

Moreover, claims 6 to 9 and 11 are drafted in the form of the first medical indication, although it is not possible to patent the same substance or the same composition for any other use of this nature (see EPO examination guidelines C-IV 4.2).

Therefore the present application fails to meet the requirements of PCT Article 33(1) since the subject matter of claims 6 to 9 and 11 does not involve an inventive step within the meaning of PCT Article 33(3).

D1 is considered the prior art closest to the subject matter of claims 6 to 9 and 11.

The subject matter of claims 6 to 9 and 11 differs from D1 in that the compositions mentioned are used for a different purpose.

The problem addressed by the present invention can thus be considered that of preparing compositions containing partial dopamine agonists. The solution proposed in claims 6 to 9 and 11 of the present application cannot be considered inventive since compositions containing partial dopamine agonists are already provided by D1 (PCT Article 33(3)).

The applicant should note that the validity of the priority claim of the present application has not been checked. It should further be noted that WO02100350, which was not used for this written opinion, may become relevant when the application enters the regional phase (PCT Rule 64.3).